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EXAMINER	
KOHUT, DAVID M	
ART UNIT	PAPER NUMBER
3626	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,919	BRUSCHI ET AL.	
	Examiner	Art Unit	
	DAVID M. KOHUT	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-19,21-31 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-19,21-31 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. This communication is in response to the amendment filed on 19 December 2007. The following has occurred: claims 1, 13, and 23-24 have been amended; claims 8, 20, and 32 have been cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-6, 9-19, 21, 23-30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight, Publication No. 2002/0099570, reference A on the previously attached PTO-892, in view of Thomas et al., Publication No. 2004/0078238, reference B on the previously attached PTO-892, and Saeed et al., U.S. Patent No. 6,915,266, reference D on the previously attached PTO-892.

4. As per claim 1, Knight teaches a method for identifying clinical trial candidates (see abstract of Knight), the method comprising: receiving from a patient clinical data source, patient data including identities of patients (see page 3, paragraph 0058, lines 1-4 of Knight); forwarding the patient data to a clinical trial candidate identification service (see page 3, paragraph 0058, lines 1-4 of Knight); and receiving from the clinical trial candidate identification service a clinical trial candidate proposal corresponding to a proposed clinical trial candidate (see page 3, paragraph 0058 of Knight). However, Knight does not explicitly teach the method wherein identities of the patients are

replaced, determined, and forwarded thereby allowing anonymity. Thomas et al., however does teach a method comprising the steps of: replacing the identities of the patients in the patient data with secure patient codes (see page 2, paragraph 0014, lines 4-7 of Thomas et al.); determining an identity of the proposed clinical trial candidate from the secure patient code (see page 3, paragraph 0017, lines 13-17 of Thomas et al.); and forwarding the identity of the proposed clinical trial candidate to a candidate contact (see page 3, paragraph 0017, lines 13-17 of Thomas et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate these features into the method of Knight. One of ordinary skill in the art would have been motivated to combine these features in order to provide an apparatus and method for anonymizing medical data with improved patient file continuity and to share data between hospitals and research and design facilities both internal and external to a given hospital while protecting patient confidentiality (see page 1, paragraph 0002, lines 10-14, and paragraph 0007, lines 1-3 of Thomas et al.). In addition, neither Knight nor Thomas et al. explicitly teach the method wherein the database contains transactions. Saeed et al., however, teaches a method which has a database containing transactions between health care providers and payers (see column 9, lines 21-29 of Saeed et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight and Thomas et al. One of ordinary skill in the art would have been motivated to combine these features in order to conduct audits and information tracking (see column 9, lines 28-29 of Saeed et al.).

5. As per claim 2, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Thomas et al. further teaches the method wherein the candidate contact is a health care provider of the candidate (see page 3, paragraph 0017, lines 13-17 of Thomas et al.).

6. As per claim 3, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Knight further teaches the method wherein the candidate contact is the proposed clinical trial candidate (see page 4, paragraph 0070, lines 11-14 of Knight).

7. As per claim 4, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Thomas et al. further teaches the method wherein the step of replacing the identities of the patients in the patient data with secure patient codes comprises encrypting the identities to create secure patient codes (see page 2, paragraph 0014, lines 4-7 of Thomas et al.); and the step of determining an identity of the proposed clinical trial candidate comprises decrypting the secure patient code corresponding to the proposed clinical trial candidate (see page 3, paragraph 0017, lines 13-17 of Thomas et al.).

8. As per claim 5, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Thomas et al. further teaches the method wherein the step of replacing the identities of the patients in the patient data with secure patient codes comprises replacing the identities with unique codes and maintaining a table correlating the identities with the unique codes (see page 2, paragraph 0015, lines 10-21 of Thomas et al.); and the step of determining an identity of the proposed clinical trial

candidate comprises looking up in the table an identity of a patient corresponding to the secure patient code (see page 3, paragraph 0017, lines 13-17 of Thomas et al.).

9. As per claim 6, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Thomas et al. further teaches the method further comprising the step of extracting patient medical information from the patient data received from a patient clinical data source (see page 3, paragraph 0017, lines 10-13 of Thomas et al.).

10. As per claim 9, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Thomas et al. further teaches the method wherein the clinical data source is a hospital network (see page 1, paragraph 0002, lines 10-12 of Thomas et al.).

11. As per claim 10, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Knight further teaches the method further comprising the steps of: receiving from the candidate contact a status of the clinical trial candidate proposal (see page 4, paragraph 0070, lines 11-14 of Knight); and forwarding the status to the clinical trial candidate identification service (see page 4, paragraph 0070, lines 11-14 of Knight).

12. As per claim 11, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Knight further teaches the method wherein the status includes the identity of the proposed candidate (see page 4, paragraph 0070, lines 11-14 of Knight). Thomas et al. further teaches the method further comprising the step of replacing the identity of the proposed candidate with a secure patient code before

forwarding the status to the clinical trial candidate identification service (see page 2, paragraph 0015, lines 10-21 of Thomas et al.).

13. As per claim 12, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. Knight further teaches the method further comprising the steps of: receiving from the clinical trial candidate identification service, descriptive information about a clinical trial of the clinical trial candidate proposal (see page 6, paragraph 0099, lines 3-6 of Knight); and forwarding the information to the candidate contact (see page 6, paragraph 0099, lines 3-6 of Knight).

14. As per claim 13, Knight teaches a method for identifying clinical trial candidates (see abstract of Knight), the method comprising: receiving at least one clinical data record (see page 3, paragraph 0058, lines 1-4 of Knight); receiving a candidate selection criterion for a clinical trial (see page 3, paragraph 0058 of Knight); searching the at least one clinical data record for a matching clinical data record based on the candidate selection criteria (see page 3, paragraph 0058 of Knight); and if a matching clinical data record is found, then forwarding a contact request from the matching clinical data record (see page 4, paragraph 0070, lines 11-14 of Knight). However, Knight does not explicitly teach the method wherein each record includes a secure patient code thereby allowing anonymity. Thomas et al., however does teach a method wherein each record includes clinical data and a secure patient code uniquely identifying the record without revealing an identity of a corresponding patient (see page 2, paragraph 0014, lines 4-7 of Thomas et al.); and forwarding a contact request including at least a secure patient code from the matching clinical data record (see page

3, paragraph 0017, lines 13-17 of Thomas et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate these features into the method of Knight. One of ordinary skill in the art would have been motivated to combine these features in order to provide an apparatus and method for anonymizing medical data with improved patient file continuity and to share data between hospitals and research and design facilities both internal and external to a given hospital while protecting patient confidentiality (see page 1, paragraph 0002, lines 10-14, and paragraph 0007, lines 1-3 of Thomas et al.). In addition, neither Knight nor Thomas et al. explicitly teach the method wherein the database contains transactions. Saeed et al., however, teaches a method wherein the at least one clinical data record is received from an entity controlling a database containing transactions between health care providers and payers (see column 9, lines 21-29 of Saeed et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight and Thomas et al. One of ordinary skill in the art would have been motivated to combine these features in order to conduct audits and information tracking (see column 9, lines 28-29 of Saeed et al.).

15. As per claim 14, Knight, Thomas et al., and Saeed et al. teach the method of claim 13 as described above. Thomas et al. further teaches the method wherein the contact request is forwarded to a trusted entity having an identity of a patient corresponding to the forwarded secure patient code (see page 3, paragraph 0017, lines 13-17 of Thomas et al.).

16. As per claim 15, Knight, Thomas et al., and Saeed et al. teach the method of claim 13 as described above. Thomas et al. further teaches the method wherein the secure patient code is an encrypted identity of a patient (see page 2, paragraph 0014, lines 4-7 of Thomas et al.).

17. As per claim 16, Knight, Thomas et al., and Saeed et al. teach the method of claim 13 as described above. Thomas et al. further teaches the method wherein the secure patient code is a unique code corresponding to an entry in a table accessible to a trusted entity (see page 2, paragraph 0015, lines 10-21 of Thomas et al.).

18. As per claim 17, Knight, Thomas et al., and Saeed et al. teach the method of claim 13 as described above. Knight further teaches the method further comprising the step of receiving descriptive information about the clinical trial, and wherein the contact request includes the descriptive information (see page 6, paragraph 0099, lines 3-6 of Knight).

19. As per claim 18, Knight, Thomas et al., and Saeed et al. teach the method of claim 13 as described above. Thomas et al. further teaches the method wherein the at least one clinical data record is received from a data exchange service (see page 2, paragraph 0013, lines 2-6 of Thomas et al.).

20. As per claim 19, Knight, Thomas et al., and Saeed et al. teach the method of claim 18 as described above. Thomas et al. further teaches the method wherein the secure patient code corresponding to a matching clinical data record is forwarded to the data exchange service (see page 2, paragraph 0014 of Thomas et al.).

21. As per claim 21, Knight, Thomas et al., and Saeed et al. teach the method of claim 13 as described above. Thomas et al. further teaches the method wherein a secure patient code corresponds to a matching clinical data record (see page 2, paragraph 0014 of Thomas et al.). And Saeed et al. further teaches a method wherein the clinical data record is forwarded to an entity controlling a database containing transactions between health care providers and payers (see column 9, lines 21-29 of Saeed et al.).

22. As per claim 23, Knight teaches a method for selecting clinical trial candidates (see abstract of Knight), the method comprising the steps of: periodically receiving clinical data records, each said record including clinical data (see page 3, paragraph 0058, lines 1-4 of Knight); and periodically searching the data records to identify records of clinical trial candidates (see page 3, paragraph 0058, lines 15-18 of Knight). However, Knight does not explicitly teach the method of a secure patient code. Thomas et al., however, does teach the method comprising a secure patient code uniquely identifying the record without revealing an identity of a corresponding patient (see page 2, paragraph 0015, lines 10-21 of Thomas et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate these features into the method of Knight. One of ordinary skill in the art would have been motivated to combine these features in order to provide an apparatus and method for anonymizing medical data with improved patient file continuity and to share data between hospitals and research and design facilities both internal and external to a given hospital while protecting patient confidentiality (see page 1, paragraph 0002, lines 10-14, and

paragraph 0007, lines 1-3 of Thomas et al.). In addition, neither Knight nor Thomas et al. explicitly teach the method wherein the database contains transactions. Saeed et al., however, teaches a method which has a database containing transactions between health care providers and payers (see column 9, lines 21-29 of Saeed et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight and Thomas et al. One of ordinary skill in the art would have been motivated to combine these features in order to conduct audits and information tracking (see column 9, lines 28-29 of Saeed et al.).

23. System claims 24-30 and 33 repeat the subject matter of claims 23, 1, 10, 13, 4-6, and 9 (respectively) as a set of "means-plus-function" elements rather than a series of steps. As the underlying process has been shown to be fully disclosed by the teachings of Knight, Thomas et al., and Saeed et al. in the above rejection of claims 23, 1, 10, 13, 4-6, and 9, it is readily apparent that the Knight, Thomas et al., and Saeed et al. references include a system to perform the recited functions. As such, these limitations are rejected for the same reasons provided in the rejection of claims 23, 1, 10, 13, 4-6, and 9 and incorporated herein.

24. Claims 7 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight, Publication No. 2002/0099570, reference A on the previously attached PTO-892, in view of Thomas et al., Publication No. 2004/0078238, reference B on the previously attached PTO-892, Saeed et al., U.S. Patent No. 6,915,266, reference D on the previously attached PTO-892, and Thangaraj et al., Publication No. 2003/0208378, reference C on the previously attached PTO-892.

25. As per claim 7, Knight, Thomas et al., and Saeed et al. teach the method of claim 1 as described above. However, none of the references explicitly teach the method of reformatting the data. Thangaraj et al., however, does teach the method comprising the step of reformatting the patient data received from a patient clinical data source (see page 2, paragraph 0019, lines 6-11 of Thangaraj et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight, Thomas et al., and Saeed et al. One of ordinary skill in the art would have been motivated to combine these features to allow data to be captured from and provided to a number of different data sources regardless of data format (see page 2, paragraph 0019, lines 1-3 of Thangaraj et al.).

26. System claim 31 repeats the subject matter of claim 7 as a set of "means-plus-function" elements rather than a series of steps. As the underlying process has been shown to be fully disclosed by the teachings of Knight, Thomas et al., Saeed et al., and Thangaraj et al. in the above rejection of claim 7, it is readily apparent that the Knight, Thomas et al., Saeed et al., and Thangaraj et al. references include a system to perform the recited functions. As such, these limitations are rejected for the same reasons provided in the rejection of claim 7 and incorporated herein.

27. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knight, Publication No. 2002/0099570, reference A on the previously attached PTO-892, in view of Thomas et al., Publication No. 2004/0078238, reference B on the previously attached PTO-892, Saeed et al., U.S. Patent No. 6,915,266, reference D on the

previously attached PTO-892, and Smith et al., U.S. Patent No. 5,111,395, reference E on the previously attached PTO-892.

28. As per claim 22, Knight, Thomas et al., and Saeed et al. teach the method of claim 13 as described above. However, none of the references explicitly teach the method wherein a contact request is only sent once for each clinical data record. Smith et al., however, does teach a method comprising the steps of: maintaining records of matching data records (see column 2, lines 35-44 of Smith et al.); and wherein the step of forwarding a contact request including a secure patient code is performed only if that code has not already been forwarded (wherein the secure patient code is a contact name and number in the prior art) (see column 2, lines 35-44 of Smith et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight, Thomas et al., and Saeed et al. One of ordinary skill in the art would have been motivated to combine these features in order to eliminate duplicate records (see column 1, line 40 of Smith et al.).

Response to Arguments

29. In the remarks filed 19 December 2007, Applicant argues in substance that (1) claims 1, 13, 23, and 24, as amended, are patentable over the combination of Knight, Thomas and Saeed because there is no suggestion to combine Knight and Thomas, and no suggestion to combine Saeed with the other two; and (2) all remaining claims depend directly or indirectly from claims 1, 13, 23, and 24, and are patentable for the same reasons.

30. In response to Applicant's argument (1), Examiner respectfully contends that there is motivation to combine Knight with Thomas et al. Thomas et al. states that "in order to properly support research and development ...data will often need to be shared between hospitals and research and design facilities both internal and external to a given hospital" (see page 1, paragraph 0002, lines 9-12 of Thomas et al.). However, in order to share this data, the patient's confidentiality needs to be protected (see page 1, paragraph 0002, lines 12-14 of Thomas et al.). Therefore, combining the method of identifying clinical trial candidates of Knight with the method of anonymizing data of Thomas et al. would have been obvious in order to share confidential data. Therefore, Examiner does not find Applicant's argument to be persuasive. In addition, the Examiner is using the Saeed et al. reference to show that it is well known in the art to receive a clinical data record from an entity controlling a database containing transactions between health care providers and payers. Saeed et al. does, in fact, teach this method. It would be obvious to combine Saeed et al. with the other references since the information from this database could be used to **track** candidates for clinical trials (see column 9, lines 27-29 of Saeed et al.). Therefore, Applicant's argument is not found to be persuasive.

31. In response to Applicant's argument (2), since Examiner does not find Applicant's argument (1) to be persuasive, Applicant's argument (2) is not found to be persuasive since it is founded upon the same reasoning.

Conclusion

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Kohut, Esq. whose telephone number is 571-270-1369. The examiner can normally be reached on M-Th 730-5 w/1st Fri off. 2nd Fri 730-4.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

36. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. M. K./
Examiner, Art Unit 3626
3/18/2008

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626